Applicant	Focus Diagnostics, Inc. 11331 Valley View Street Cypress, California 90630 USA
Establishment Registration No.	2023365
Contact Person	Tara Viviani tel 714.822.2115 fax 714.822.3898 tviviani@focusdx.com
Summary Date	May 18, 2010
Proprietary Name	Simplexa™ Influenza A H1N1 (2009)
Generic Name	Influenza A H1N1 2009 Real Time RT-PCR
Classification	Class II, Special Controls
Predicate Devices	Luminex Diagnostics XTAG RESPIRATORY VIRAL PANEL (K091667, K081483, K063765) CDC Human Influenza Virus Real-Time RT- PCR Detection and Characterization Panel (K080570)

MAY 24 2010

Intended Use

The Focus Diagnostics Simplexa™ Influenza A H1N1 (2009) assay is intended for use on the 3M Integrated Cycler as part of the Microfluidic Molecular System for the *in vitro* qualitative detection and differentiation of influenza A and 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), and nasopharyngeal aspirates (NPA) from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2009-2010 influenza season when 2009 H1N1 influenza was the predominant influenza A virus in circulation. When other Influenza A viruses are emerging, performance characteristics may vary.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Device Description

Simplexa™ Influenza A H1N1 (2009) test kit is a nucleic acid amplification test that uses real-time reverse transcriptase polymerase chain reaction (RT-PCR) amplification to enable simultaneous and distinct detection of influenza A and 2009 H1N1 influenza in a single reaction from nasopharyngeal swabs (NPS), nasal swabs (NS), and nasopharyngeal aspirates (NPA). The assay combines real-time PCR amplification with fluorescent signal detection technology. A bi-functional fluorescent probe-primer is used together with a reverse primer to amplify a specific target (for each analyte and internal control). A fluorescent signal is generated after the separation of the fluorophore from the quencher as a result of the binding of a probe element to the extended RNA fragment synthesized during amplification.

The 3M Integrated Cycler is a rapid real-time Polymerase Chain Reaction thermocycler used for the identification of nucleic acid from prepared biological samples. The instrument utilizes disk media to contain and to process samples. The instrument uses real time flourometric detection to identify targets within the sample wells. The instrument is controlled by an external computer running the Integrated Cycler Studio Software. Together, the instrument, software and test kit are referred to as the "Microfluidic Molecular System."

Predicate Device Information

Trade Name / Method	510(k) submitter	510(k) number	Decision Date	Panel	Product Code(s)
XTAG Respiratory Viral Panel – FluA	Luminex	K091667 K081483 K063765	06/25/2009 06/25/2008 11/30/2007	Microbiology (83)	OCC, OEM, OEP
CDC Human Influenza Virus Real-Time RT-PCR Detection and Characterization Panel	Centers for Disease Control and Prevention	K080570	09/30/2008	Microbiology (83)	NXD, OEP, OCC, NSU

Item	Device	Predicate	
Name	Simplexa™ Influenza A H1N1 (2009)	xTAG Respiratory Viral Panel – FLUA	CDC Human Influenza Virus Real-Time RT- PCR Detection and Characterization Panel
Intended Use	The Focus Diagnostics Simplexa™ Influenza A H1N1 (2009) assay is intended for use on the 3M Integrated Cycler as part of the Microfluidic Molecular System for the *in vitro* qualitative detection and differentiation of influenza A and 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), and nasopharyngeal aspirates (NPA) from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Performance characteristics for influenza A were established during the 2009-2010 influenza season when 2009 H1N1 influenza was the predominant influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infection with a novel Influenza A virus is suspected	The xTAG® Respiratory Viral Panel (RVP) is a qualitative nucleic acid multiplex test intended for the simultaneous detection and identification of multiple respiratory virus nucleic acids in nasopharyngeal swabs from individuals suspected of respiratory tract infections. The following virus types and subtypes are identified using RVP: Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B, Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus, Human Metapneumovirus, Rhinovirus, and Adenovirus. The detection and identification of specific viral nucleic acids from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection if used in conjunction with other	The Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel (rRT-PCR Flu Panel) is intended for use in Real-time RT-PCR assays on an ABI 7500 Fast Dx Real-time PCR instrument in conjunction with clinical and epidemiological information: * for qualitative detection of influenza virus type A or B in symptomatic patients from viral RNA in nasopharyngeal and/or nasal swab specimens, * for determination of the subtype of seasonal human influenza A virus, as seasonal A/HI or A/H3, if present, from viral RNA in nasopharyngeal and/or nasal swab specimens, * for presumptive identification of virus in patients who may be infected with influenza A subtype A/H5 (Asian lineage) from viral RNA in human respiratory specimens and viral culture in conjunction with clinical

Item	Device	Predicate	
Name	Simplexa™ Influenza A H1N1 (2009)	xTAG Respiratory Viral Panel – FLUA	CDC Human Influenza Virus Real-Time RT- PCR Detection and Characterization Panel
	based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	clinical and laboratory findings. It is recommended that specimens found to be negative for Influenza B, Respiratory Syncytial Virus subtype A and B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3 and Adenovirus, after examination using RVP be confirmed by cell culture. Negative results do not preclude respiratory virus infection and should not be used as the sole basis for diagnosis, treatment or other management decisions. Positive results do not rule out bacterial infection, or co-infection with other viruses. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial culture, immunofluorescence, radiography) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory viral infection. Due to seasonal prevalence, performance characteristics for Influenza A/H1 were established primarily with retrospective specimens. The RVP assay cannot adequately detect Adenovirus species C, or serotypes 7a and 41. The RVP primers for detection of rhinovirus cross-react with enterovirus. A rhinovirus reactive result	and epidemiological risk factors. * to provide epidemiologic information for surveillance for influenza viruses. Performance characteristics for influenza A were established when influenza A/H3 and A/HI were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. Testing with the influenza H5a and H5b primer and probe sets should not be performed unless the patient meets the most current U.S. Department of Health and Human Services (DHHS) clinical and epidemiologic criteria for testing suspect A/H5 specimens. The definitive identification of influenza A/H5 (Asian lineage) either directly from patient specimens or from virus cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. All users, analysts, and any person reporting diagnostic results from use of this device should be trained to

Item	Device	Predicate	
Name	Simplexa™ Influenza A H1N1 (2009)	xTAG Respiratory Viral Panel – FLUA	CDC Human Influenza Virus Real-Time RT- PCR Detection and Characterization Panel
		should be confirmed by an alternate method (e.g. cell culture). Performance characteristics for Influenza A Virus were established when Influenza A/H3 and A/H1 were the predominant Influenza A viruses in circulation. When other Influenza A viruses are emerging, performance characteristics may vary. If infections with a 2009 H1N1 Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for 2009 H1N1 virulent Influenza viruses and sent to a state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.	perform and interpret the results from this procedure by a CDC instructor or designee prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed training provided by CDC instructors or designees.
Assay Targets	Influenza A 2009 H1N1 Influenza	Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Respiratory Syncytial Virus subtype A, Respiratory Syncytial Virus subtype B, Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus, Human Metapneumovirus, Rhinovirus, and Adenovirus.	Inlfluenza A/H1 Influenza A/H3 Influenza A/H5 (asian lineage) Influenza B
Sample Types	NPS, NS, NPA	NPS	NPS, NS, viral culture

Item Name	Device	Predicate	
	Simplexa™ Influenza A H1N1 (2009)	xTAG Respiratory Viral Panel – FLUA	CDC Human Influenza Virus Real-Time RT- PCR Detection and Characterization Panel
Extraction Methods	Roche MagNA Pure LC Total Nucleic Acid Isolation Kit, QIAGEN QIAamp Viral RNA Mini Kit	QIAGEN QIAamp Mini Elute Biomérieux EasyMag, Biomérieux MiniMag	QIAamp® Viral RNA Mini Kit. Qiagen RNeasy® Mini Kit, MagNA Pure LC RNA Isolation Kit II Roche MagNA Pure LC Total Nucleic Acid Isolation Kit,
Assay Methodology	PCR-based system for detecting the presence / absence of viral RNA in clinical specimens	PCR-based system for detecting the presence / absence of viral DNA/RNA in clinical specimens	PCR-based system for detecting the presence / absence of viral RNA in clinical specimens
Detection Techniques	Multiplex assay using different reporter dyes for each target.	Multiplex assay using a combination of color coded beads and different reporter dyes.	A panel of oligonucleotide primers and dual-labeled hydrolysis (TaqMan®) probes for the qualitative detection and differentiation of influenza virus type and subtype target sequences.
Influenza A Viral Target	Well conserved region of the matrix gene	Well conserved region of the matrix gene	Well conserved region of the matrix gene
H1N1 (2009) Viral Target	Well conserved region of the hemagglutinin gene specific for H1N1 (2009)	n/a	n/a
LoD	Influenza A Strains $TCID_{50}$/mL in a range of $1x10^{-1}$ to $2.7x10^{1}$ 2009 H1N1 $TCID_{50}$/mL in a range of $1x10^{-1}$ to $2.7x10^{1}$ Please refer to detailed table below.	Influenza A A/PR/8/34 ($TCID_{50}$/mL = $8x10^{-1}$) A/Victoria/3/75 ($TCID_{50}$/mL = $1x10^{2}$)	Influenza A A/New Caledonia/20/1999 ($TCID_{50}$/mL = $10^{1.2}$) A/Hawaii/15/2001 ($TCID_{50}$/mL = $10^{1.5}$) A/New York/55/2004 ($TCID_{50}$/mL = $10^{2.2}$) A/Wisconsin/67/2005 ($TCID_{50}$/mL = $10^{1.2}$)
Reproducibility	FLUA Inter-Assay Total %CV range 0.0 to 4.8 FLUA Intra-Assay Total %CV range 0.0 to 6.6 H1N1 Inter-Assay Total %CV range 0.0 to 1.8 H1N1 Intra-Assay Total %CV range 0.0 to 4.7	Influenza A - low positive %CV range 29.41 to 60.22 Influenza A - medium titer %CV range 5.6 to 35.6	Influenza A – 1:10 of low positive %CV range 1.94 to 7.09 Influenza A – low positive %CV range 2.12 to 7.89

Reproducibility:

Three investigative sites assessed the device's inter-laboratory reproducibility and inter/intra-assay reproducibility. Each of the three laboratories tested eighteen samples, the Positive Control and the No Template Control, in triplicate on five different days. Each site had two operators who each ran the assay once per day, for a total of two runs per day. Two sites performed the extraction using the MagNA Pure LC Total Nucleic Acid Isolation Kit; one site performed the extraction step using the Qiagen QIAamp Viral RNA Mini Kit. Combined results for all sites are summarized below.

FLUA Inter-Assay	Total %CV range (0.0 to 4.8)
FLUA Intra-Assay	Total %CV range (0.0 to 6.6)
H1N1 Inter-Assay	Total %CV range (0.0 to 1.8)
H1N1 Intra-Assay	Total %CV range (0.0 to 4.7)

Limit of Detection

Simplexa™ Influenza A H1N1 (2009) Limit of Detection – FLUA

Influenza A Strain	LoD MagNA Pure extraction ($TCID_{50}$/mL)		LoD QIAgen extraction ($TCID_{50}$/mL)	
	Swab	Aspirate	Swab	Aspirate
A/California/7/2009 NYMC x-179-A	$1.3x10^{1}$	$1.3x10^{1}$	$1.3x10^{1}$	$2.7x10^{1}$
A/Swine NY/02/2009 H1N1	$1x10^{-1}$	$1x10^{-1}$	$1x10^{-1}$	$1x10^{-1}$
A/Solomon Island/03/06 H1	$5x10^{0}$	$5x10^{0}$	$1x10^{0}$	$1x10^{0}$
A/Brisbane/59/07 H1	$1x10^{0}$	$1x10^{0}$	$1x10^{0}$	$1x10^{0}$
A/Brisbane/10/07 H3	$1x10^{-1}$	$1x10^{-1}$	$5x10^{-1}$	$5x10^{-1}$
A/Wisconsin/67/05 H3	$1x10^{-1}$	$5x10^{-1}$	$1x10^{-1}$	$1x10^{-1}$

Simplexa™ Influenza A H1N1 (2009) Limit of Detection – H1N1

2009 Influenza A Strain	LoD MagNA Pure extraction ($TCID_{50}$/mL)		LoD QIAgen extraction ($TCID_{50}$/mL)	
	Swab	Aspirate	Swab	Aspirate
A/California/7/2009 NYMC x-179-A	$1.3x10^{1}$	$2.7x10^{1}$	$2.7x10^{1}$	$2.7x10^{1}$
A/Swine NY/02/2009 H1N1	$1x10^{-1}$	$1x10^{-1}$	$1x10^{-1}$	$1x10^{-1}$

Analytical Reactivity

Influenza A Strain	Estimated LoD
A/PR/8/34 H1N1	$1x10^{0}$
A/New Caledonia/20/99 H1N1	$1x10^{0}$
A/Taiwan/42/06 H1N1	$1x10^{1}$
A/WS/33 H1N1	$1x10^{0}$
A/Hong Kong/8/68 H3N2	$1x10^{0}$

Cross-Reactivity

No cross reactivity was detected for either Influenza A or 2009 H1N1 to organisms that are closely related to influenza A or 2009 H1N1, or cause similar clinical symptoms as influenza A or 2009 H1N1, or present as normal flora in the specimen types of interest.

Interference

Potentially interfering substances were not tested with this methodology; common medications taken by study participants do not appear to inhibit the PCR process.

Clinical Agreement

Specimens were prospectively collected at three sites from patients with signs and symptoms of influenza like illness (Austin, TX (September 2009) and the New South Wales region of Australia (July – September 2009). Specimens were blinded and randomly distributed to 3 U.S. clinical laboratories for testing. Specimens were determined to be positive for 2009 H1N1 influenza by a composite reference method including the Luminex xTAG RVP Flu A target, a validated PCR assay using primer and probe sequences published by the CDC and a well characterized PCR followed by sequencing. Two results were generated for each specimen, an influenza A result and a 2009 H1N1 influenza sub-typing result. Both results must be positive to determine that a specimen is 2009 H1N1 influenza positive.

299 prospectively collected nasal/nasopharyngeal swabs and 112 nasopharyngeal aspirates were analyzed using the Simplexa™ Influenza A H1N1 (2009) assay. The data presented below are stratified by both result and specimen type. Fifteen (15) specimens (10 swabs and 5 aspirates) were excluded from the analysis because there was no consensus among the reference assays for the influenza A result. Twelve (12) specimens (9 swabs and 3 aspirates) were excluded from the 2009 H1N1 Influenza Clinical Agreement Summary tables as sequencing data used to determine subtype was not available. These 12 specimens are included in the Influenza A Clinical Agreement Summary tables.

2009 H1N1 Influenza Clinical Agreement Summary

Simplexa™ Influenza A H1N1 (2009) vs. Composite Reference Result – Prospectively Collected Swabs[1]

		H1N1 Result - Simplexa™ Influenza A H1N1 (2009)			
		n	H1N1 Detected	H1N1 Not Detected	% Agreement
Composite Reference Result	H1N1 Detected	101	101	0	% Positive Agreement 100%(101/101) 95% CI:96.3-100%
	H1N1 Not Detected	179	8	171	% Negative Agreement 95.5%(171/179) 95% CI:91.4-97.7%

1) Ten (10) samples were excluded from the analysis because there was no consensus among the influenza A reference assays. Nine (9) samples were excluded because sequencing results to determine sub-types were not available.

2009 H1N1 Influenza Clinical Agreement Summary

Simplexa™ Influenza A H1N1 (2009) vs. Composite Reference Result – Prospectively Collected Aspirates[1]

		H1N1 Result - Simplexa™ Influenza A H1N1 (2009)			
		n	H1N1 Detected	H1N1 Not Detected	% Agreement
Composite Reference Result	H1N1 Detected	24	24	0	% Positive Agreement 100%(24/24) 95% CI:86.2-100%
	H1N1 Not Detected	80	6	74	% Negative Agreement 92.5%(74/80) 95% CI:84.6-96.5%

1) Five (5) samples were excluded from the analysis because there was no consensus among the influenza A reference assays. Three (3) samples were excluded because sequencing results to determine sub-types were not available.

Influenza A Clinical Agreement Summary

Simplexa™ Influenza A H1N1 (2009) vs. Composite Reference Result – Prospectively Collected Swabs[1]

		Influenza A Result - Simplexa™ Influenza A H1N1 (2009)			
Composite Reference Result		n	Influenza A Detected	Influenza A Not Detected	% Agreement
	Influenza A Detected	116	116	0	% Positive Agreement 100%(116/116) 95% CI:96.8-100%
	Influenza A Not Detected	173	13	160	% Negative Agreement 92.5%(160/173) 95% CI:87.6-95.6%

1) Due to the low prevalence of other strains of influenza A during the testing period, all FLU A responses from prospectively collected swabs were combined to demonstrate the performance of the FLU A bi-functional fluorescent primer-probe. Of the 116 specimens determined to be positive for FLU A: 101 were 2009 H1N1 influenza positive, zero (0) were H1N1, four (4) were H3N2, two (2) were not detected by the alternate PCR and could not be sequenced, and nine (9) were not sub-typed. Ten (10) samples were excluded from the analysis because there was no consensus among the influenza A reference assays.

Influenza A Clinical Agreement Summary

Simplexa™ Influenza A H1N1 (2009) vs. Composite Reference Result – Prospectively Collected Aspirates[1]

		Influenza A Result - Simplexa™ Influenza A H1N1 (2009)			
Composite Reference Result		n	Influenza A Detected	Influenza A Not Detected	% Agreement
	Influenza A Detected	31	31	0	% Positive Agreement 100%(31/31) 95% CI:89-100%
	Influenza A Not Detected	76	3	73	% Negative Agreement 96.1%(73/76) 95% CI:89-98.6%

1) Due to the low prevalence of other strains of influenza A during the testing period; all FLU A responses from prospectively collected aspirates were combined to demonstrate the performance of the FLU A bi-functional fluorescent primer-probe. Of the 31 specimens determined to be positive for FLU A, 24 were 2009 H1N1 influenza positive, one (1) was sequenced but the sub-type could not be determined, three (3) were not detected by the alternate PCR and could not be sequenced, three (3) did not have sufficient volume to sequence to determine sub-type. Five (5) samples were excluded from the analysis because there was no consensus of the influenza A reference assays.

An additional 214 retrospectively collected nasal/nasopharyngeal swabs and 2 nasal washes from the Focus Sample Bank were also tested at 3 sites. Three (3) swab specimens were excluded from the analysis because there was no consensus among the reference assay results. One (1) swab specimen was excluded from the 2009 H1N1 Influenza Clinical Agreement Summary tables as sequencing data used to determine subtype was not available. This specimen is included in the Influenza A Clinical Agreement Summary tables.

2009 H1N1 Influenza Clinical Agreement Summary

Simplexa™ Influenza A H1N1 (2009) vs. Composite Reference Result – Retrospectively Collected Swabs[1]

		H1N1 Result - Simplexa™ Influenza A H1N1 (2009)				
Composite Reference Result		n	H1N1 Detected	H1N1 Not Detected	Indeterminate	% Agreement
	H1N1 Detected	57	57	0	0	% Positive Agreement 100%(57/57) 95% CI:93.7-100%
	H1N1 Not Detected	153	13	139	1	% Negative Agreement 90.8%(139/153) 95% CI:85.2-94.5%

1) Three (3) samples were excluded from the analysis because there was no consensus of the influenza A reference assays. One (1) sample was excluded from the analysis because sequencing results there was insufficient sample to perform sequencing.

Two retrospectively collected washes were found to be positive for 2009 H1N1 influenza by the composite reference method and by the Simplexa assay.

Influenza A Clinical Agreement Summary

Simplexa™ Influenza A H1N1 (2009) vs. Composite Reference Result – Retrospectively Collected Swabs[1]

		Influenza A Result - Simplexa™ Influenza A H1N1 (2009)				
Composite Reference Result		n	Influenza A Detected	Influenza A Not Detected	Indeterminate	% Agreement
	Influenza A Detected	132	131	0	1	% Positive Agreement 99.2%(131/132) 95% CI:95.8-99.9%
	Influenza A Not Detected	79	13	66	0	% Negative Agreement 83.5%(66/79) 95% CI:73.9-90.1%

1) Due to the low prevalence of other strains of influenza A during the testing period; all FLU A responses from retrospectively collected samples were combined to demonstrate the performance of the FLU A bi-functional fluorescent primer-probe. Of the 132 specimens determined to be positive for FLU A, 57 were 2009 H1N1 influenza positive, two (2) were H1N1, 59 were H3N2, one (1) was sequenced but the sub-type could not be determined, one (1) was indeterminate by Simplexa, 11 were not detected by the alternate PCR and could not be sequenced, and one (1) did not have sufficient volume to sequence to determine sub-type. Three (3) samples were excluded from the analysis because there was no consensus of the influenza A reference assays.

Two retrospectively collected washes were found to be positive for influenza A by the composite reference method and by the Simplexa assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Focus Diagnostics, Inc.
c/o Tara Viviani
Regulatory Affairs Project Manager
11331 Valley View St.
Cypress, California 90630

MAY 2 4 2010

Re: k100148

Trade/Device Name:	Simplexa ™ Influenza A H1N1 (2009)
Regulation Number:	21CFR §866.3332
Regulation Name:	Influenza A H1N1 2009 Real Time RT-PCR
Regulatory Class:	Class II
Product Code:	OQW
Dated:	April 27, 2010
Received:	April 29, 2010

Dear Ms. Viviani:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a

legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100148

Device Name: Simplexa™ Influenza A H1N1 (2009)

Indications for Use:

The Focus Diagnostics Simplexa™ Influenza A H1N1 (2009) assay is intended for use on the 3M Integrated Cycler as part of the Microfluidic Molecular System for the *in vitro* qualitative detection and differentiation of influenza A and 2009 H1N1 influenza viral RNA in nasopharyngeal swabs (NPS), nasal swabs (NS), and nasopharyngeal aspirates (NPA) from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

Performance characteristics for influenza A were established during the 2009-2010 influenza season when 2009 H1N1 influenza was the predominant influenza A virus in circulation. When other Influenza A viruses are emerging, performance characteristics may vary.

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k100148